510(K) SUMMARY (06/11/12)

[As required by 21 CFR §§ 807.87 and 807.92]

XenX™

510(k) Number K113692

AUG 9 2012

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Trade Name:
XenX™

Classification Name:
Endoscopic guidewire, gastroenterology-urology AND dislodger, stone, basket, ureteral, metal

Classification:
FDA has classified these types of devices as class II devices (product codes OCY and FFL) and they are reviewed by the Gastroenterology/Urology panel.

Basis for Submission:
New device

Predicate Devices:
- Sensor Nitinol Guidewire, Boston Scientific Corp, 510(k) Exempt
- Roadrunner PC Wire Guide, Cook Urological Inc, K082536
- Stone Cone Nitinol Urological retrieval coil, Boston Scientific Corp, K970121
- Accordion urological occluding guidewire, Percsys, K052048
- NTrap stone entrapment and extraction device, Cook Urological Inc, K863081

Device Description:
The XenX device combines several features in one device which facilitate an endoscopic procedure. The XenX easily tracks past ureteral kidney stone and is navigated under fluoroscopy like a urologic guidewire. Once in place, a self-expandable braided structure is deployed to block the ureteral lumen and prevent stone particle migration towards the kidney. The braided structure enables a constant irrigation flow for clear uretroscopic vision during the procedure. Following stone fragmentation and if required the physician can choose to propagate a urinary stent over the device for ureteral placement.

Intended Use:
The XenX device is intended to be used endoscopically to bypass and entrap calculi from the urinary tract, to prevent retrograde migration of calculi during laser lithotripsy,and to facilitate the placement of endourological instruments during diagnostic or interventional procedures.

Technological Characteristics:

The XenX consist of a braided tubular mesh compacted into a guidewire-shaped device.

Performance Data
The following nonclinical testing were performed to demonstrate the performance and safety of XenX as compared to its predicate devices

- Tip flexibility test
- Deployment/retrieval force
- Stenting compatibility
- Tensile strength
- Pushability test
- Radial expansion
- Particle sieving
- Radiopacity test

Testing showed that the XenX is as safe, effective and performs as well as, or better than the predicates.

Substantial Equivalence

Characteristic	Sensor	Roadrunner	NTrap	Stone cone	Accordion	XenX
Intended use	Intended to facilitate the placement of endourological instruments during diagnostic or interventional procedures.	Used for ureteral access to establish a tract, and assist in the placement, replacement and exchange of devices during urological procedures includes use in a torturous or kinked ureter traversing a large stone in route to the kidney or in cases demanding enhanced control and high radiopacity.	Used as an endoscopic entrapment and extraction device for calculi and other foreign bodies in the urinary tract, and to minimize stone migration during laser, electrohydraulic or pneumatic lithotripsy	Intended to be used endoscopicall y to entrap and remove calculi and other foreign objects from the urinary tract.	Intended to be used endoscopically to entrap and remove calculi and other foreign objects from the Urinary tract and to guide instrumentation within the ureteral tract.	The XenX device is intended to be used endoscopically to bypass and entrap calculi from the urinary tract, to prevent retrograde migration of calculi during laser lithotripsy,and to facilitate the placement of endourological instruments during diagnostic or interventional procedures
Location of use	Urinary tract	Urinary tract	Urinary tract	Urinary tract	Urinary tract	Urinary tract
Technological characteristics	Boston Scientific offers the Sensor guidewire with PTFE coatings; hydrophilic coatings for reduced friction; Nitinol core for kink reduction and a flexible tip to facilitate navigation.	Cook Wire Guides consist of a Nitinol core for kink resistance coated with a polymer sleeve, and hydrophilically coated to reduce friction.	NiTi extractor retrieval basket, interlaced and interweaved together wires, creating a special shape that will not allow urinary tract stones or other objects to fall out at the extraction stage as well as ensuring their easy capture, it is manually deployed by retracting the basket out of	The Stone Cone Nitinol urological retrieval coil consists of a nitinol core wire with a PTFE coating. The wire assembly is housed in a sheath. The sheath is provided to straighten the device coil during placement and withdrawal; coil is	The ACCORDION Urological Occluding Guidewire consists of a film membrane pre-loaded within a two-part guidewire it is activated by a removable handle. The folded membrane acts to entrap stone fragments during lithotripsy. The hydrophilic	The XenX device incorporates a nitinol core wire, a floppy, polyurethane-coated hydrophilic tip for easy stone passage and kink resistance with a very thin and flexible nitinol-based self-expandable braid/sieve structure as an integral part of the guide wire.

Characteristic	Sensor	Roadrunner	NTrap	Stone cone	Accordion	XenX
			sheath.	manually deployed by retracting the cone out of sheath.	coated Nitinol tip is offered to enable easy stone passage	The braid is housed in a sheath and is manually deployed out of the sheath.
Mode of operation	Inserted into the ureter past the stone to establish a tract and assist in the placement, replacement and exchange of devices during urological procedures	Inserted into the ureter past the stone to establish a tract and assist in the placement replacement and exchange of devices during urological procedures.	Inserted into the ureter in its closed configuration; once past the stone the retention basket is deployed to prevent stone migration during lithotripsy; larger stone fragments can be swept into the bladder following treatment.	Inserted in the ureter in its closed configuration, once past the stone the retention cone is deployed to prevent stone migration during lithotripsy; larger stone fragments can be swept into the bladder following treatment.	Inserted into the ureter in its straightened un-deployed film configuration similar to a guidewire, once past the stone the multi fold film is formed. The device's film conforms to and fills the ureter to prevent retrograde migration of stone fragments. Following fragmentation; The device can sweep larger stone fragments into the bladder	Inserted in the ureter in its un-deployed guidewire mode, once past the stone the self expandable braid is deployed, braid conforms to and fills the ureter to prevent retrograde migration of stone fragments.
Material made	Nitinol core wire PTFE coat, Polyurethane coat, Hydrophilic coating, Tungsten filled radiopaque tip	Nitinol core, Platinum coil, Hydrophilic coat, Polyurethane jacket	Nitinol core wire, Nitinol woven mesh basket, Polyimide outer sheath	Nitinol core wire PTFE coated, Polymeric sheath	Nitinol core wire, PTFE coated, Hydrophilic tip, Polymeric occlusion film	Nitinol core wire Nitinol braid mesh, Polyurethane coat, Tungsten filled radiopaque tip, Hydrophilic Nitinol braided mesh coating, Polyimide outer sheath
Principal of operation	Advancement of the flexible tip past the stone until located at the desired anatomical	Advancement of the flexible tip past the stone until located at the desired anatomical	Inserted past occluding stone while basket is retracted within outer sheath, followed by basket	Inserted past occluding stone while cone is retracted within outer sheath,	Inserted past stone while occluding film is in its straight configuration, followed by folding the	Inserted while braid is retracted within outer sheath, the flexible tip is advanced past

Characteristic	Sensor	Roadrunner	NTrap	Stone cone	Accordion	XenX
	location	location	deployment	followed by cone deployment.	occluding film.	the stone until the desired anatomical location is reached, followed by deployment of occluding braid.

The XenX combines guide-wire and stone retention functionalities in one device. In its guidewire configuration it is substantially equivalent in its introduction, function, intended use and technology to the Sensor and Roadrunner guidewires and to the Accordion device. Once the self-expanding braid is deployed the XenX acts as a retention device and is substantially equivalent to the Stone-cone, Ntrap and Accordion devices in all characteristics excluding stone particle retrieval (sweeping functionality) which is not claimed as one of XenX features. This makes the XenX safer and less invasive in comparison with its predicate retention devices. Using the XenX, stone particles can be disintegrated by lithotripsy down to 1mm size, allowing them to easily pass through the urine system, hence the sweeping function becomes irrelevant.

Conclusion:

Xenolith Medical Ltd. believes that, based on the information provided in this submission, XenX™ is substantially equivalent to its predicate devices without raising any new safety and/or effectiveness issue.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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AUG 9 2012

Re: K113692
Trade/Device Name: XenX™
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCY, FFL
Dated: July 24, 2012
Received: July 30, 2012

Dear Mr. Zigman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K113692

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XenX™

Indications for Use:

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Prescription Use _X____ (Per 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K113692